

### **REMARKS**

Applicant has carefully reviewed the Final Office Action mailed on July 13, 2004. Applicant respectfully traverses all objections, rejections, and assertions made by the Examiner. Claims 23-38 are pending.

#### **Claim Rejections Under 35 U.S.C. § 102**

Claims 23-26, 29-32 and 35-38 are rejected under 35 U.S.C. § 102(b) as being anticipated by Schwab et al. (U.S. Patent No. 5,876,376). Applicant respectfully traverses the rejection.

The Schwab et al. patent is directed to a balloon catheter having a coaxial guidewire catheter and a distal tip extension attached to the distal end of the guidewire catheter and extending distally from the balloon.

Schwab et al. do not disclose the invention of claim 23, as the distal tip extension 30 of Schwab et al. does not meet the elements of a tie layer as claimed. For instance, claim 23 recites "the heat shrunk tubular member being heat shrunk to the inner tubular member", while Schwab et al. disclose heat bonding the overlapping area of the guidewire shaft and the distal tip extension to form the tip component 10. Column 2, lines 31-33. Heat shrinking is a process compatible with certain materials, where heat is applied to shrink the dimensions of the material. Heat bonding is a different process, where two or more materials are melted together using heat to bring the surfaces of the materials above their melting temperatures. While Schwab et al. disclose heat shrinking, they use heat shrinking only to reduce the inner diameter of a distal portion of tip extension 30.

Moreover, tip extension 30 of Schwab et al. has a tie layer which is substantially longer than the distal waist length. Distal tip extension 30 cannot be modified to meet the elements of the tie layer insert of claim 23. If the distal tip extension of Schwab et al. is reduced in length to be substantially the same length as the distal waist length, it will not be able to extend distally from the distal end of the balloon tail and, therefore, will not be the separate, flexible tip that is the essence of the catheter of Schwab et al. Col. 3, lines 2-5.

Applicant therefore submits that claim 23 is patentable over Schwab et al. Applicant also submits that claims 24-26, which depend from claim 23 and contain additional elements, are in condition for allowance.

Schwab et al. also do not disclose every element of claim 29, which recites “a tie layer insert having a length that is substantially the same as the distal waist length”. As mentioned above with respect to claim 23, the distal tip extension of Schwab et al. is substantially longer than the distal waist of the balloon. Applicant thus submits that claim 29 is patentable over Schwab et al. As claims 30-32 depend from claim 29 and contain additional claim elements, Applicant submits that these claims are in condition for allowance as well.

Neither does Schwab et al. disclose every element of claim 35, which recites “the multi-layer insert having a length that is substantially the same as the length of the distal portion of the balloon”. Schwab et al. disclose neither a multi-layer insert nor, as described above, an insert that is substantially the same length as the distal portion of the balloon. Applicant thus submits that claim 35 is in condition for allowance.

Schwab et al. do not disclose every element of claim 36, either. Claim 36 recites, for example: “providing a balloon having a proximal waist, a distal waist...the distal waist having a length that is substantially the same length as the tie layer”. As described above with respect to claim 23, the tie layer of the catheter of Schwab et al. is substantially longer than the distal waist of the balloon. Applicant thus submits that claim 36 is in condition for allowance. As claims 37-38 depend from claim 36 and contain additional elements, Applicant submits that these claims are in condition for allowance as well.

Claims 29, and 33-34 were rejected under 35 U.S.C. § 102(b) as being anticipated by Miki et al. (U.S. Patent No. 6,706,010). Applicant respectfully disagrees.

Miki et al. disclose a balloon catheter where the distal waist of the balloon is bonded to a guidewire shaft with an adhesive 21. (Figures 11 and 12.) Applicant's claim 29 recites that the tie layer insert is thermally bonded to both the distal waist and the distal end region of the second tubular member. Typical adhesives do not meet these structural requirements. Instead, adhesives typically bind structures when the adhesive “cures”, for example, by evaporation of a solvent in which the adhesive is dissolved in or through the process of a chemical reaction. Moreover, Miki et al. teach away from using a heat curing adhesive at column 21, lines 33-39:

“When a heat curing adhesive agent is used, the catheter shaft and balloon are inevitably exposed to heat during the heating required for curing. As a result, it is entirely possible that the balloon diameter will shrink, the balloon bursting pressure will decrease,

and the catheter shaft will undergo thermal degradation, and these all lead to diminished balloon catheter performance, so the use of a heat curing adhesive agent is not advised.”

Accordingly, Miki et al. do not disclose or teach the claimed tie layer. Applicant therefore respectfully submits that Miki et al. do not anticipate claim 29 or claims 33-34 which depend therefrom and contain additional elements.

Claim 29 was rejected under 35 U.S.C. § 102(b) as being anticipated by Burns et al. (U.S. Patent No. 5,176,698). Applicant respectfully traverses the rejection.

Burns et al. teach a balloon catheter where the distal segment of the balloon member is bonded to the distal end of a second inner tube using an adhesive such as epoxy. Column 4, lines 17-19. As described above with respect to Miki et al., an adhesive is not a tie layer thermally bonded to the distal waist of the balloon and a distal region of a second tubular member. Applicant thus submits that claim 29 is not anticipated by Miki et al.

Claim 29 was rejected under 35 U.S.C. § 102(b) as being anticipated by Campbell et al. (U.S. Patent No. 3,675,367). Applicant disagrees and respectfully traverses the rejection.

Campbell et al. teach a balloon catheter where one or both of the waists of the balloon may be wrapped with a securing band to create a controlled failure zone. The balloon distal waist may also be secured to a coaxial catheter using an adhesive. See, for example, column 5, lines 44-59. As described above with respect to Miki et al., an adhesive does not meet the requirements of claim 29 of a tie layer insert. Applicant thus submits that claim 29 is not anticipated by Campbell et al.

### **Claim Rejections under 35 U.S.C § 103**

Claims 27-28 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Schwab et al. as applied to claim 23, and further in view of Miki et al.

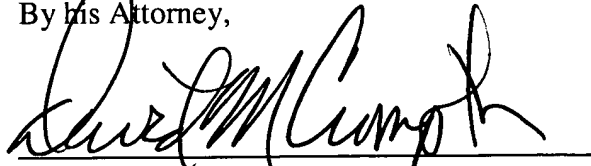
Claims 27-28 depend from claim 23, which Applicant submits is patentable, and contain additional elements. Moreover, the teaching of polyethylene and polytetrafluoroethylene from Miki et al., as suggested by the Examiner, does not eliminate the deficiency of Schwab et al. as discussed above. For these reasons, Applicant submits that claims 27-28 are also in condition for allowance.

Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Lixiao Wang

By his Attorney,

A handwritten signature in black ink, appearing to read "David M. Crompton", written over a horizontal line.

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